K042372

EXHIBIT 2

510(k) Summary

OCT 0 4 2004

VATECH
Value Added Technology Co., Ltd.
75-11, Seokwoori, Dongtanmyun,
Hwasungsi, Kyunggido,
445-811, Korea
Tel: 82-31-377-9104
Fax: 82-31-377-1882
Chang Joon Ro, President & CEO
July 29, 2004

1. Identification of the Device:
   Proprietary-Trade Name: "HDS" Intra-oral Imaging System
   Classification Name: Extraoral source x-ray system, Product Code 90 MUH
   Common/Usual Name: Intra-oral digital x-ray sensor

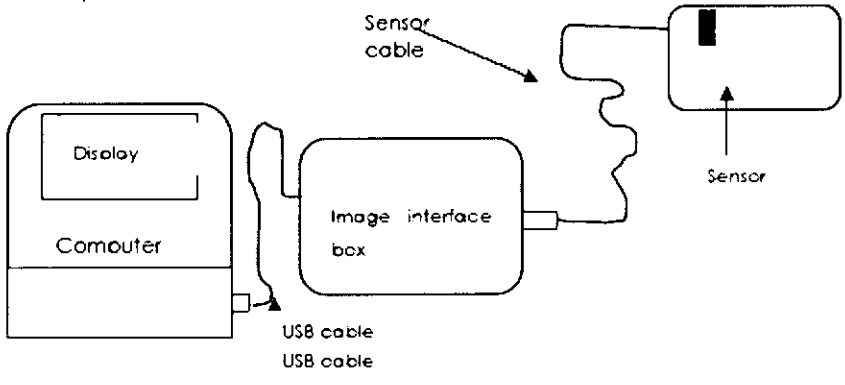
2. Equivalent legally marketed device: This product is similar in design and identical in function to the Suni Intraoral Imaging System (K021718, Suni Imaging Microsystems Inc.)

3. Indications for Use (intended use): Indicated for intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

4. Description of the device: The Intra-oral image system (HDS) is a device for digital intra oral X-rays imaging. It is fully USB compliant and can be plugged in any when computer is turned on.

Intra-oral image system (HDS) block diagram

- PC
- Image interface box (Read-out Box)
- X-ray sensor



5. Safety and Effectiveness, comparison to predicate device:

Feature	Predicate: Suni Intraoral Imaging System (K021718)	Intraoral Imaging System (HDS)
Intended Use	Intra-oral Imaging System is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.	SAME
Computer interface	USB (USB version not specified)	SAME, Specification 2.0
Pixel Matrix	271,000, 462,000, 1.26 M, or 1.8 M pixels, depending on model	650,000 pixels (688 × 944 pixel)
Pixel Size	22.5 or 45 um (depending on model)	35 um
Active Area	26.8 x 21.6 mm 32.7 x 20.6 mm 36.8 x 26.6 mm 36.8 x 26.6 mm	24.08 mm x 33.04 mm
External Dimensions	32.5 x 26.4 mm 37.8 x 24.7 mm 43.0 x 31.8 mm 43.0 x 31.8 mm Thickness 3.2 mm	29 × 41 mm Thickness 3.5 mm
Spatial Resolution	12 lp/mm (Standard res model)	14 lp/mm
Applicable PC	Computer requirements not specified.	-Software: Pentium 3,1 GHz -Memory size: 128 MB -Hard disk: 10GB -VGA; 1024x768x24 bit -Other: Window XP, Serial USB port

6. Testing information and Conclusion
In all material respects, the "HDS" Intra-oral Imaging System is substantially equivalent to Suni Intraoral Imaging System (K021718, Suni Imaging Microsystems Inc.) Testing was performed according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2004

VATECH Value Added Tech., Co., Ltd.
% Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box. 7007
DEERFIELD IL 60015

Re: K042372
Trade/Device Name: "HDS" Intra-Oral Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: August 30, 2004
Received: September 13, 2004

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042372

Device Name: "HDS" Intra-oral Imaging System

Indications For Use: "HDS" Intra-oral Imaging System is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

Prescription Use X ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042372